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REMARKS

Claims 1-4 and 6-14 are pending in the application. Claim 1 is the only independent claim and has been amended herein.

The drawings were objected to under 37 CFR 1.83(a) as failing to show "the position of the tabs as described in the specification" and also as failing to show "the fluid connection between lumen 118 and the second interior volume". Applicants respectfully submit that each of these is clearly shown in the figures as filed. Specifically, Figures 1A-1C collectively show the inner tube 122 (Figs. 1A-1C), and tabs 119 extending from inner tube 122 (Figs. 1B and 1C). In addition, Figure 1A shows the "fluid connection" between lumen 118 and skive 126 (see also the specification at page 14, lines 27-28). Figure 1A is a "side schematic view", while Figures 1B and 1C are cross-sectional views of the catheter shown in Figure 1A taken along the lines 1B-1B shown in Figure 1A. Together, these figures clearly show the structural detail that is essential for a proper understanding of the disclosed invention. Withdrawal of the objection to the drawings is therefore respectfully requested.

Claims 1-4 and 6-14 were rejected under 35 USC 112, second paragraph, as being indefinite. The amendments made herein to Claim 1 are believed to address the comments noted that "to be in the path of the first interior volume filling fluid...between the inner and outer tubes". Specifically, Claim 1 not recites that the "working fluid, input into a second interior volume, defined between the inner tube and the inner balloon, passes said radially extending tabs, and is not unduly impeded by said radially extending tabs". In addition, the specification does "positively associate the tabs with the balloons", as it recites (at least at page 6, lines 22-25) that "the device may further comprise at least two radially extending tabs disposed around a circumference of the inner tube to substantially center the inner tube within the dual balloon". Reconsideration and withdrawal of the Section 112 rejection are respectfully requested.

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Claims 1-4, 6-11 and 13-14 were rejected under 35 USC 103(a) as being unpatentable over US Patent 5,868,735 (Lafontaine) in view of US Patent 5,106,360 (Ishiwara et al.) and further in view of newly-cited US Patent 4,445,892 (Hussein et al.). Claim 12 was rejected as being unpatentable over Lafontaine, Ishiwara and Hussein, and further in view of US Patent 6,063,101 (Jacobsen et al.). Claims 13-14 were rejected as being unpatentable over Lafontaine, Ishiwara, Hussein, and further in view of US Patent 4,497,721 (Ginsburg).

The previous rejection based upon Lafontaine, Amplantz and Ginsburg was withdrawn.

In view of the foregoing amendments and the following comments, each of the outstanding rejections is respectfully traversed and reconsideration is requested.

Claim 1, as amended herein, is directed to a device to treat tissue including an outer tube, an inner tube disposed at least partially within the outer tube and including a guidewire lumen, a supply lumen and a return lumen, and a dual balloon. The duel balloon includes an inner balloon and an outer balloon, the inner balloon coupled to the inner tube at a proximal end and at a distal end, the outer balloon coupled to the inner tube at a distal end and to the outer tube at a proximal end. A first interior volume, defined between the outer balloon and the inner balloon, is in fluid communication with an inlet in the volume between the outer tube and the inner tube, and at least two radially extending tabs, extending from the inner tube, are disposed around a circumference of the inner tube to substantially center the inner tube within the dual balloon. Working fluid, input into a second interior volume, defined between the inner tube and the inner balloon, passes the radially extending tabs, and is not unduly impeded by the radially extending tabs.

The Action takes the position that Lafontaine teaches all of the limitations of the claim except (1) a lumon to fill the volume between the balloons, and (2) spacers for maintaining position of elements". The Action then relies upon the alleged teachings of Ishiwara to arrive at limitation (1), and upon the alleged teachings of Hussein to arrive at limitation (2). two radially extending tabs — Amplantz et al. disclose a balloon catheter that includes tab members to anchor the inner lumen of the catheter within the balloon while inflated [t]herefore, it would have been obvious...to include two tab members to anchor the inner lumen within the balloon when inflated".

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For at least the foregoing reasons, independent Claim 1, as amended herein, is believed to be patentable over any permissible combination of the teachings of Lafontaine, Ishiwara, Hussein, Ginsburg and Jacobson, and reconsideration is requested.

Dependent Claims 2-4 and 6-14 are believed to be clearly patentable for all of the reasons indicated above with respect to Claim 1, and even further distinguish over the cited references by reciting additional limitations.

Since the Applicants have fully responded to the Office Action, it is respectfully submitted that in regard to the above remarks that the pending application is patentable over the art of record and prompt review and issuance is accordingly requested. Should the Examiner be of the view that an interview would expedite consideration of this Amendment Rejection or of the application at large, request is made that the Examiner telephone the Applicants' undersigned attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,

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First, Applicants submit that reference numeral 42 of Lafontaine is a 'chamber' not a "balloon". The "chamber 42" of Lafontaine is "sized such that coolant entering the chamber from the coolant intake will evaporate in the chamber prior to exiting through the exhaust lumen" (col. 6, lines 15-17). Lafontaine further notes that "chamber 42 can be made from polyimide" (col. 3, lines 26-27). Lafontaine clearly does not teach or suggest that chamber 42 is a balloon – but rather describes at col. 4, lines 22-30, that "balloon 14 is dilated by forcing fluid into balloon 14 through inflation lumen 30 with pump 18...[c]oolant is then released into chamber 42 from a pressurized container or pump...". For at least the foregoing reasons, Applicants respectfully submit that Lafontaine does not even teach or suggest a 'dual balloon'.

Since "chamber 42" of Lafontaine is not a "balloon", there would be no reason for one of ordinary skill in the art to even consider modifying the "chamber" to include tab members (or, what the Action calls, "spacers").

The Action relies upon Hussein as providing a teaching (acknowledged to be missing from both Lafontaine and Ishiwara) of a dual balloon catheter with spacers. First, Applicants note that Hussein is directed to a 'dual balloon catheter' in which two balloons are *spaced apart from one another along an elongated tubular structure, defining an occluded segment or operating region* therebetween. As noted at col. 7, lines 46-50 of Hussein, "the first balloon 234 is in fluid communication with a conduit defining the first fluid passageway 242...[and] [I]ikewise the second fluid passageway 244, defined by a conduit within inner tube 224, is for the expansion and collapse of the second balloon 236". Elongated spacer member 308 and 310 of Hussein are provided "on a carrier collar 298" and are located between the earrier collar 298 and the inside wall surface of outer tube 220.

Therefore, it is respectfully submitted that Hussein does not teach or suggest Applicants claimed "radially extending tabs, extending from an inner tube, disposed around a circumference of the inner tube to substantially center the inner tube within the dual balloon" – and even if Hussein did provide such teaching (which again, it does not) – Lafontaine teaches away from such a modification, as Lafontaine's device has a chamber (rather than a balloon).